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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,726	10/01/2002	Shun-ichiro Matsumoto	6235-62514	6930

24197 7590 12/19/2005

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EXAMINER	
BASI, NIRMAL SINGH	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 12/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/088,726	MATSUMOTO ET AL.	
	Examiner	Art Unit	
	Nirmal S. Basi	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 October 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-27* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-4, 6, 15, 18-20 and 25, drawn to nucleic acids, vectors, transformants and method of recombinantly producing protein.

Group II, claim(s) 5, and 21, in so far as they are drawn to polypeptides.

Group III, claim(s) 7 and 26, drawn to method of screening for ligands that bind to the protein of claim group II.

Group IV, claim(s) 8 and 27, drawn to method of screening for compounds that have activity of inhibiting the binding between the protein of group II and a ligand.

Group V, claim(s) 9-10, drawn to method of screening for compounds that suppress or enhance the activity of the protein of group II to transduce a signal into a cell via the activation of the G protein of group II.

Group VI, claim(s) 11 and 17 drawn to antibody.

Group VII, claims(s) 12-14, drawn to compound isolated by the method of group III.

Group VIII, claim 16, drawn to method for diagnosing a disease selected from the group consistingof cancer, cirrhosis, and Alzheimer's disease, comprising detecting expression of the DNA of group I in tissues related to the disease derived from a subject, or mutation in the DNA of group I in the subject.

Group IX, claims(s) 22, drawn to compound isolated by the method of group IV.

Group X, claims(s) 23 and 24, drawn to compound isolated by the method of group V.

The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: "the special technical features" is defined in PCT Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. Since claim 1 encompasses "isolated DNA encoding a protein comprising the amino acid sequence of SEQ ID NOs: 1, 2, 3, 4, 17, 18, 19, 20, or 21 in which one or more amino acids are substituted, deleted, added, and/or inserted" and Glucksmann et al., (U.S.Patent number 5,945,307, issued 8/31/1999), disclose a GPCR nucleic acid (SEQ ID NO:1) encoding a GPCR polypeptide (SEQ ID NO: 2), that contains isolated DNA encoding a protein comprising the amino acid sequence of SEQ ID NOs: 1, 2, 3, 4, 17, 18, 19, 20, or 21 **in which one or more amino acids are substituted, deleted, added, and/or inserted the protein of claim 1** is not a technical feature that defines a contribution over the prior art. The polynucleotide of Glucksman encompasses the technical feature due to the substituted, added, inserted and deleted amino acids of the isolated DNA encoding a protein comprising the amino acid sequence of SEQ ID NOs: 1, 2, 3, 4, 17, 18, 19, 20, or 21 of instant invention leads to the GPCR of SEQ ID NO:1 and SEQ ID NO:2 of Glucksman.

The articles of manufacture lack the same or corresponding special technical features because they are compositions comprising a polypeptide, nucleic acid, antibody and unidentified compounds, each of which are compounds which are structurally and functionally different from each other and each of which can be made and used without the other. The methods of assay or screening require polypeptide, polynucleotide or an antibody, each of which are different compounds, which are structurally and functionally different from each other and each of which can be made and used without the other.

The claims of Group I-X are drawn to a multitude of nucleic acids (SEQ ID NOs.5-8, 22-26), proteins (SEQ ID NOs.1-4, 17-21) and methods of their use . The claims apply to numerous structurally and functionally different nucleic acids and their encoded polypeptides. This constitutes recitation of an implied, mis-joined Markush group that contains **multiple, independent and distinct inventions**. Each of the different nucleic acids/polypeptides/antibodies/and methods of use are independent and distinct because no common structural or functional properties are shared. Accordingly, these claims are subject to restriction under U.S.C. 121 and 372. Upon election of Groups I-X,

Applicants is additionally required to elect a single nucleic acid and its encoded polypeptide that corresponds to the elected group. This requirement is not to be constructed as a requirement for election of species, since each of the compounds recited in alternative form is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.

Although classifications for the nucleic acids, proteins, antibodies are overlapping, for instance 536/23.1, each represents a patentably distinct product, having different sequences for the nucleic acids of group II, different amino acid sequences, structures and activities for the polypeptides of group I, and different amino acid sequences and binding specificities for the antibodies of group III, and each would require separate sequence searches. Furthermore, searching the different polypeptide inventions groups II and VI would not be used to determine the patentability of any of the other polypeptides, for example.

Applicants are advised that this is not a species election.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Rejoinder Under Ochiai/Brouwer

The examiner has required restriction between product and process claims. Where Applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04.

Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or notice of allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in

accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal S. Basi whose telephone number is 571-272-0868. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa can be reached on 571-272-0829. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nirmal Basi NB
Art Unit 1646
December 9, 2005

JOSEPH MURPHY
PATENT EXAMINER